William Paterson University

Institutional Review Board (IRB)

Protocol Application Package for Faculty & Staff

William Paterson University is deeply concerned with safeguarding the rights and welfare of all human subjects who participate in research conducted under its aegis. Through the Institutional Review Board for Human Subject Research (IRB), the University reviews, approves and monitors all research by faculty, staff and outside researchers, as well as some students.

Most research involving living human beings that is conducted by a member of the WPU community must be submitted to the IRB for review and then approved prior to the initiation of the research. Research that is the subject of a proposal to a funding agency receives a preliminary review prior to its submission, then a complete review when it is funded. The types of research that are not submitted to the IRB are detailed in the IRB Policy (see below).

The instructions, forms and samples included in this package are for use by WPU faculty and staff only.

> Different processes and forms are used for research submitted by WPU's undergraduate and graduate students, as well as for outside researchers (faculty, students and others who are not part of the WPU community). Instructions and related forms are available on the WPU IRB's webpage: www.wpunj.edu/osp/irb

The IRB's oversight role and the protocol submission and review process are defined in detail in the Policy in the *Use of Human Subjects in Research at WPUNJ (the IRB Policy, last revised in 2005).* The philosophical foundation for the use of human subjects in research is in *The Belmont Report: Ethical Principals and Guidelines for the Protection of Human Subjects in Research* (The National Commission for the Protection of Human Subjects of Biomedical Behavioral Research, 1979), and the Federal guidelines for human research protection is codified in 45 CFR 46 - Basic DHHS Policy for Protection of Human Research Subjects - Subpart A. Copies of these documents, as well as WPU's forms and related information, are available on or through the Office of Sponsored Programs' IRB webpage: http://www.wpunj.edu/osp/irb.

Certification of Training in the Use of Human Subjects in Research

All investigators and senior personnel on research projects involving human subjects must have completed a training program in the use of human subjects in research in order for their protocol to be accepted for review. If you have not completed this training and have a certificate on file with the WPU IRB, please click here for additional information.

Submission of a Protocol for Review

Complete instructions are included in the IRB Policy concerning the format and content of a protocol, requirements for informed consent, the protection of data and subject confidentiality, and other issues related to a research project involving human subjects. This package is not a

substitute or repetition of the information included in the IRB Policy. This package only provides the forms required for submission, an outline of the minimum categories of information that should be included in the protocol's narrative, and samples of documents that may be needed as part of your research.

Once submitted and accepted for review, the IRB's review has two stages. The first is a review and finding by two members of the IRB. Questions may be offered during this review as well as requests for modifications to forms, processes or data collection tools. Once the initial reviewers are satisfied that human subjects are adequately protected and that the research falls within the bounds of the Federal designations for Exempted or Expedited Review, they approve the protocol and the investigator is notified that they may start their research. If approved by the initial reviewers, the second stage is a review by the full IRB, after which other questions, concerns or modifications may be offered or requested. If the initial reviewers decide that the protocol requires a full committee review, it is placed on the agenda for the next committee meeting or a special meeting is called to review the protocol.

Please plan for the submission of your protocol appropriately based on when you would like to begin involving human subjects in your research activities. In general, the review a proposal that is deemed to fit either the Exempted or Expedited categories will be completed between ten (10) and fifteen (15) days while a Full Review will probably take a minimum of thirty (30) days.

For your planning purposes, the following are summaries of the Federal review categories that the WPU IRB uses to determine which types of review (Exempted, Expedited and Full) is appropriate for a protocols. The IRB Policy provides additional information for each item.

Research that is not submitted to the WPU IRB includes:

- Research conducted by WPU in which the subjects are its constituencies and the research is related to the mission and goals of the University.
- Research evaluating the conduct or outcome of a project, program, course or other activity sponsored by the University unless that evaluation is the intent of the project, program, course or other activity.
- Pedagogical research that is conducted by the instructor of the students involved in the research.
- Oral histories that are not medically related.

To be considered for Exempted reviews, the research will have no impact on subjects and fall within these broad categories:

- educational research
- educational tests
- surveys, interviews
- observation of public behavior
- no vulnerable populations
- existing data, document pathological or diagnostic specimen
- publicly available information
- demonstration project for public benefit
- taste and food quality
- evaluation and assessment of WPU program

To be considered for Expedited reviews, the research will have a minimal impact on subjects and fall within these broad categories:

- noninvasive collection of hair/nail clippings, teeth, excreta, secretions and fluids
- recording of data using noninvasive procedures, i.e.: sensors, testing sensory activity, weighing, electrocardiography
- study of existing data records and specimens collected for non-research
- voice, video, digital or other image recordings
- group behavior, games, cognition
- drugs or devices that do not require an IND or ID exemption
- exercise of healthy volunteers
- collection of blood samples of 50ml. or 3ml./kg. not more than 2 times per week for 8 weeks.
- Continuing reviews

A full review will be required for all other types of research.

Approval Notice Signature Requirement

After a protocol is approved, the approval notice is sent to the Principal Investigator(s) for signature and return to the IRB. The approved research may not begin until the IRB has acknowledged the return of the signed approval notice. When the notice and the acknowledgement are emailed to the investigators, the investigator's department chair (or dean if the investigator is a department chair) will be copied. A copy of the resolution concerning this requirement is included in this packet.

This package contains the following items:

1. Protocol Checklist
2. Appendix A Protocol Face Sheet
3. Sample Informed Consent Statements and Related Items

William Paterson University
Institutional Review Board (IRB)

IRB Protocol Checklist

1. **IRB Protocol Face Sheet with signatures**

2. **Protocol narrative, including:**

   a. Research abstract (one paragraph)

   b. Research design (background/need; model/theory/procedures to be used; one or more pages)

   c. Methodology: (two or more pages)
      1. How do you propose to conduct the research, what do you intend to do with the subjects, where will you do it, when will you do it, how will you protect your data?
      2. How do you propose to select your subjects? How will you protect them?
      3. What are the benefits of conducting the research?
      4. What are the risks of conducting the research
      5. What is your anticipated outcome? What do you expect to produce as a result of the research?

   d. Informed consent. Every proposal must include an "informed consent statement" insures each subject's voluntary participation; parent consent forms for minors and children must include the child's name and how their assent to participate will be obtained.

   e. Attachments. Copies of proposed tests/questionnaires, support letters, brochures, recruitment letters/emails, information on potential research project funding agencies and applicable program(s). See Face Sheet for number of copies of required items.

3. **Deliver one copy of the IRB Protocol Application package to:**

   Institutional Review Board
   Office of Sponsored Programs
   Raubinger Hall, Room 309
   William Paterson University, Wayne, NJ 07470

   Questions or concerns?
   Contact the Office of Sponsored Programs at 973-720-2852, Fax: 973-720-3573, or visit the OSP and IRB webpage: www.wpunj.edu/osp

WILLIAM PATERSON UNIVERSITY

Protocol No.: _____

Date Received: _____
For IRB Use Only

Institutional Review Board for Human Subject Research

APPENDIX A: PROTOCOL FACE SHEET

For use by WPUNJ Faculty and Staff and by Outside Researchers

Instructions: Submit one original protocol prior to the initiation of any work involving human subjects or human material to the IRB Administrator c/o the Office of Sponsored Programs, Raubinger Hall, Room 107. A complete protocol includes: (1) a completed and signed Appendix A: Protocol Face Sheet, (2) a complete description of the research plan, (3) single copies of all test instruments, and (4) all informed consent statements. IRB Training Certification, if not on file with the IRB, and the WPUNJ Conflict of Interest and Commitment Disclosure Form, if not on file with the OSP, must be attached as well for each investigator listed below.

Principal Investigator,
Title and Department _____
Campus Mailing Address _____
Campus Phone, Email Address _____
Other Investigators _____
Project Title

_____

Research Dates Beginning: _____ Ending: _____
If Applicable:
Funding Agency or Sponsor _____
OSP Proposal Number _____

PLEASE ANSWER THE FOLLOWING QUESTIONS:

	Yes	No	
1.	____	____	Is this application for a fellowship/stipend only?
2.	____	____	Is this application for an internal WPU funding program? Program: _____
3.	____	____	Is this project to be undertaken as part of a previously approved research, training, program development or program implementation grant? Funding agency, project title and project director=s name and institution if not WPUNJ:
4.	____	____	Human subjects to be involved in the proposed activity are or have (mark all that apply):

____ Children or minors ____ Mental or behavioral disorder ____ Limited English Proficiency
____ Fetuses ____ Developmental disability
____ Abortuses ____ Physical disorder or disability ____ Other:
____ Pregnant women ____ WPUNJ students
____ Prisoners ____ WPUNJ employees ____ Adults

5.	____	____	Will subjects be videotaped or audiotaped?
6.	____	____	Does the project involve in-person interviews with open-ended questions?
7.	____	____	Does the project involve the use of human blood, blood products, tissues or body fluids?
8.	____	____	If Question #7 is yes, have you attended the Occupational Exposure to Blood-borne pathogens program offered by the WPU College of Science and Health?
9.	____	____	Does the project involve administration of ionizing radiation t subjects for other than clinical purposes?

	Yes	No	
10	____	____	Does the project involve the testing of investigational drugs or devices?, If YES, please provide: Name of Drug or Device _____ IND# or IDE# _____ Name of Manufacturer _____ Attach one copy of a brochure, flyer or other information concerning the drug or device.
11	____	____	Does the project involve the use of electrical apparatus at WPUNJ other than routine care equipment?
12	____	____	Are the items listed below attached to this Appendix A: Protocol Face Sheet?
13	____ there is a conflict	____ there is not a conflict	I certify that this proposal complies with the WPUNJ *Conflict of Interest and Commitment Policy* (*http://ww3.wpunj.edu/osp*). If a potential conflict may exist for me or any other senior project personnel, a *Conflict of Interest and Commitment Disclosure Form* is attached.

- Research plan: Including Purpose, Duration, Subject Recruitment and Selection, Location, Background, Research Design, Potential Risks, Consent Procedures, Protection of Subjects, Potential Benefits, and Risk/Benefit Statement.
- Data collection instruments
- Informed Consent Statements
- IRB Training Certification if not already on file with the IRB.
- WPUNJ Conflict of Interest and Commitment Disclosure Form if "yes" is checked.

Signatures:

Principal Investigator: _____ Date: _____

Other Investigator: _____ Date: _____

*Department Chairperson: _____ Date: _____

Department: _____

*Other: _____ Date: _____

Unit: _____

*The signature of each department chairperson with faculty involved, is required. A Dean's signature must be obtained if the investigator is also the chairperson. If additional signatures are required, please attach a second Page 2 for those signatures.

Training Certification Confirmation

To be completed by Principal Investigator		To be completed by IRB		
Name	Title/Role in Project	Federal Regulations	WPUNJ Policy & Procedures	Conflic of Interest Disclosure

..... For Completion by IRB Only.....

Initial Reviewer: _____ Type: _____ Decision: _____ Date: _____
Committee Review Date: _____ Affirmed: Yes ___ No ___: _____
First Continuing Review Date: _____

SAMPLE CONSENT STATEMENTS

Following are sample consent forms written in the format which is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use the bold headings provided. When you submit your consent form(s), please date them and when a revision is submitted for review, change the date.

APPENDIX D.1: Passive Informed Consent for Surveys or Questionnaires

The following is a sample consent form written in the format that is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use headings if needed. When your consent form is approved, date it with the approval date. If a revision is approved change the date on all forms used after the approval, update them as well. The name of the research project must be on each page of the statement and each page must be numbered.

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Required Heading for Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Other Investigators: _____
Faculty Sponsor: _____
Contact Phone Number: _____
Department: _____
Course Name and Number: _____
Date: _____

Required Heading for Non-Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____

****

This [insert survey or questionnaire] concerns [insert descriptive statement]. [If student research, insert: It is being conducted to fulfill the requirements of the above named course.] I understand that my participation is voluntary and I may stop completing the [insert survey or questionnaire] at any time and I do not have to answer any question(s) I choose not to answer. Risks associated with my completing this [insert survey or questionnaire] have been explained to me and I accept them. I understand that my identity will not be revealed in any way through my participation in this study; I will not write my name on this document and the results will not be reported in a way that will reveal individual participants. If I do not want to complete this [insert survey or questionnaire] I may return it uncompleted as instructed for completed documents or I may keep it. If I choose to participate, I will complete and return this document by [insert return instructions].

APPENDIX D.2.a: Active Informed Consent for Interviews and Other Minimal Risk Studies

The following is a sample consent form written in the format that is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use headings if needed. When your consent form is approved, date it with the approval date. If a revision is approved change the date on all forms used after the approval. Update them as well. The name of the research project must be on each page of the statement and each page must be numbered.

****

Required Heading for Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Other Investigators: _____
Faculty Sponsor: _____
Contact Phone Number: _____
Department: _____
Course Name and Number: _____
Date: _____

Required Heading for Non-Student Research:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____

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I have been asked to participate in a research study on [insert descriptive statement]. The purpose of this study will be to [insert descriptive statement]. I understand that I will be asked to [insert activity(s)]. Potential risks from participating in this survey include [insert list], they have been explained to me and I accept them.

I understand that my participation is entirely voluntary and I may end my participation in this research at any time. I understand that my identity will be protected at all times and that my name will not be used without my separate written permission. I understand that the results of this study will not be reported in a way that would identify individual participants. [If this is for a focus group or if multiple participants are present, insert: I understand that I must protect the identity of the other participants in this study and may not tell anyone outside this group what was said by any member of the group.]

I may call the investigators [insert name(s)] or the other individuals listed in the heading of this document if I have any questions or concerns about this research and my participation. I may call the Associate Vice President and Dean for Graduate Studies and Research (973-720-3093) for information regarding my rights as a research subject.

By signing this consent form, I am agreeing to participate in this research study.

Name of Subject_____ Signature of Subject_____
Date: _____
Name of Investigator_____ Signature of Investigator_____
Date:_____
Name of Witness_____ Signature of Witness_____
Date:_____ Include witness signature For vulnerable populations or other special needs

APPENDIX D.2.b: Active Informed Consent for Studies with More than Minimal Risk

Following is a sample consent form written in the format that is requested by the IRB. There are sections with required statements which are to be used in all consent forms and also a few sections have selected statements you may choose from depending on the type of study you are going to do. When writing your consent form(s), please use one tense throughout the document (either "I" or "You") for consistency and use the bold headings provided. When you submit your consent form(s), please date them and when a revision is submitted for review, update them as well. The name of the research project must be on each page of the statement and each page must be numbered.

****

Required Heading:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____

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INVITATION TO PARTICIPATE: I am being asked to participate in a research study because, etc.

PURPOSE: The purpose of the study should be expressed in lay language and should clearly state the nature of the research project.

PROCEDURES: The subject must be informed exactly what his/her participation will involve. This may include the length and frequency of hospitalization; types of medication; placebo administration; types and number of tests; amount of blood to be drawn (in terms a lay person can understand such as ounces, tablespoons, teaspoons); randomization; questionnaires, including the type of information to be asked; video-taping; diets; withholding of standard treatment; follow-up studies; duration of participation; etc. If a test article is involved, the consent form should explain that: 1) It is routinely used for the proposed purposes of the study; and 2) It is experimental and not approved for general use in the United States but has been approved for the use in this study.

RISKS: Describe potential physical and psychological risks in lay language.

BENEFITS: Direct or to society. If there is not direct benefit to the subject, a statement reflecting this fact must be recorded.

ALTERNATIVES: Describe in lay language how the patient would be treated if not otherwise in a research study and any potential adverse effects from the alternatives.

COMPENSATION: Describe any fees (dollar amount) to be paid to the subject for participation, describe partial payment or no payment for early termination or bonus for completion. Or a statement that there will not be financial compensation for participation.

CONFIDENTIALITY: There are two standard statements of confidentiality, one of which needs to be included in this section.

For clinical trials: I understand that all information collected in this study will be kept strictly confidential, except as may be required by law. I further understand that representatives of the Sponsor, as well as the Food and Drug Administration, may review the data collected from this study and my medical records. If any publication results from this research, I will not be identified by name.

For non-clinical trial studies: I understand that all information collected in this study will be kept strictly confidential, except as may be required by law. If any publication results from this research, I will not be identified by name.

ADDITIONAL INFORMATION: A statement that any significant new findings developed during the course of the study that may relate to the subject's willingness to continue participation will be provided to the subject. The investigator must provide the subject and the IRB with a written statement concerning any significant finding(s) that may potentially influence a subject's decision to continue participating in the study. In this circumstance the investigator must renegotiate informed consent.

For Clinical Trials involving investigational medications: I understand that there is no guarantee that I may continue receiving the medication at the end of this study.

PREGNANCY: The following statement (as is or amended as appropriate) must be included in the informed consent only if the study drug/device could effect women of child-bearing age, the unborn fetus or a women breast-feeding a child.

Due to the effect of this drug/device, there could be serious harm to unborn children (or children who are breast-feeding) and it could also jeopardize the health of the mother. In addition, it is possible that harmful side effects that are not yet known could occur to both the mother and unborn or breast-feeding child. For this reason, if I am pregnant, I will inform you and understand I will not be included in the study. If I am still capable of becoming pregnant, I will be given a pregnancy test prior to entry into the study. I also understand that I will practice a medically approved method of birth control during my participation in the study. Further, I understand that while I am taking this drug/device I should not become pregnant, and if I do become pregnant, I must discontinue the drug/device and consider termination of the pregnancy.

DISCLAIMER/WITHDRAWAL: There are two standard statements of disclaimer/withdrawal, one of which needs to be included in this section.

For medical studies: I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudicing my present or future care. I also understand that should my physician find it necessary, and/or in my best interest, he/she may withdraw me from the study.

For non-medical studies: I agree that my participation in this study is completely voluntary and that I may withdraw at any time without prejudicing my standing within William Paterson University or my class.

INJURY/COMPLICATIONS: The following statement is used in 95% of all consent forms:
I understand that in the event of an injury resulting from the research procedures, medical treatment in excess of that covered by third party payers will be provided without cost to me, but financial compensation is not available.

For studies where an adverse effect is not separately identifiable from a patient's disease process:

I understand that complications may arise during the course of therapy either due to my disease or due to the treatment. I have been advised that my doctors will carry out therapy for any such complications and third party payers may provide costs associated with such care. I have been advised that no compensation will be provided to me as a result of my participation in this study.

SUBJECT RIGHTS: I understand that if I wish further information regarding my rights as a research subject, I may contact the Assistant Vice President and Dean for Graduate Studies and Research by telephoning 973-720-3093. I also understand that if I have any questions pertaining to my participation in this particular research study, I may contact the investigator by calling the telephone number(s) listed at the top of page one. I have been given the opportunity to ask questions and have had them answered to my satisfaction.

CONCLUSION: I have read and understand the consent form. I agree to participate in this research study. Upon signing below, I will receive a copy of the consent form.

Name of Subject_____ Signature of Subject_____
Date: _____

Name of Investigator_____ Signature of Investigator_____
Date:_____

Name of Witness_____ Signature of Witness_____
Date:_____ Include witness signature For vulnerable populations or other special needs

APPENDIX D.2.c: Active Informed Consent for Venipuncture and Other Simple Invasive Procedures

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Required Heading:

William Paterson University
Project Title: _____
Principal Investigator: _____
Contact Phone Number: _____
Other Investigators: _____
Department: _____
Date: _____

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Additional consent for [insert name for procedure].

This research is studying [insert descriptive statement].

I understand that approximately [insert amount as formula and words as appropriate] of my blood will be needed. [Insert description of procedure, such as: The procedure involves placing a needle in a vein in my arm to take blood and will require no more than [insert number] minutes. Occasionally there are minor complications, and I may experience bruising, swelling and/or black and blue marks at the site.]

I understand that although the results of this test may not benefit me directly, they can be made available to your physician upon request. I understand that data collected during this study will be confidential, except as may be required by law, and any publication resulting from the research will not personally identify any participants. All risks have been explained to me and I accept them. I understand that my decision to take part in this study is voluntary and that medical care will not be affected if I refuse to participate. I may end my participation anytime without prejudice to present or future care. I will be given a copy of this consent form.

Should I wish further information regarding your rights as a research subject, I may contact the Assistant Vice President and Dean for Graduate Studies and Research at 973-720-3093.

I understand that in the event of physical injury resulting from the research procedure, medical treatment in excess of that covered by third party payers will be provided at no cost to me. I understand that financial compensation is not available for participation in this research.

By signing below, I consent to my participation in the procedure described above.

Name of Subject_____ Signature of Subject_____
Date: _____

Name of Physician_____ Physician's Phone_____
Date: _____

Name of Investigator_____ Signature of Investigator_____
Date:_____

Name of Witness_____ Signature of Witness_____
Date:_____

APPENDIX E: SAMPLE INDEMNIFICATION CLAUSE

The following is an example of an indemnification clause drawn up by the University to be used in experimental drug and device testing protocols. The signed indemnification agreement between the Trustees of William Paterson University (not an individual) and the Sponsor should be attached to the original copy of the protocol when it is submitted to the Committee on Studies Involving Human Subjects. This agreement should be forwarded as a separate document and not part of the information in an investigator agreement or a study consent form.

(Company) undertakes to indemnify, defend and hold harmless (Investigator) and Trustees of the (University), its officers, agents and employees from any and all liability, loss, damage and expenses (including attorney fees) they may suffer as the result of claims, demands, costs or judgments which may be made or instituted against them or any of them by reason of personal injury (including death) to any person or damage to property arising out of or connected with the performance of the activities to be carried out pursuant to the clinical research protocol designated as "
," Study No._____; provided, however, that any such liability, loss or damage resulting from (I) a failure to adhere to the terms of the protocol or (Company's) written instructions relative to the use of the investigational drug, (II) failure to comply with any applicable FDA or other governmental requirements or (III) negligence or willful malfeasance by (Investigator) or Trustees of the (University), its officers, agents and employees is excluded from this agreement to indemnify, defend and hold harmless.

(Investigator) and Trustees of the (University) agree to notify (Company) as soon as they become aware of a claim or action and to cooperate with and to authorize (Company) to carry out sole management and defense of such claim or action. (Company) agrees, at its own expense, to provide attorneys to defend against any actions brought or filed against (Investigator), Trustees of the (University), its officers, agents and employees with respect to the subject of indemnity contained herein, whether such claims or actions are rightfully brought or filed.

Neither (Investigator), Trustees of the (University), nor its officers, agents or employees shall compromise or settle any claim or action without the prior written approval of (Company).

_____ _____

Date Signature of Institutional Official

_____ _____

Date Signature of Manufacturer Representative

Name, address and contact information for company: _____

_____

_____

_____

_____

_____

William Paterson University
Policy on Human Subject Research at William Paterson University

Resolution Concerning Obtaining Signatures on Protocol Approval Notices
Adopted September 25, 2012

Whereas the WPU IRB requires that faculty, staff and outside investigators, as well as students in certain situations, to sign and return their Protocol Approval Notices before they begin their research, and

Whereas it has been difficult, at times, to obtain investigator signed Protocol Approval Notices back in a timely manner, and

Whereas, the Protocol Approval Notice has specific information that an investigator must acknowledge receiving, and

Whereas, the Protocol Approval Notice has specific requirements concerning continuing review, the reporting of adverse effects and other items that an investigator must accept as a condition of the approval of the protocol,

Be it resolved that:

When a Protocol Approval Notice is emailed to an investigator, the email will include:

- The requirement to the return of the signed Approval Notice within two calendar weeks after the date that the Protocol Approval Notice was sent to the investigator,

- That approval of the protocol will be suspended beginning the day after the return date whether or not the investigator is notified by the IRB,

- That approval of a suspended protocol due to failure to return an Approval Notice will be reinstated when the signed Notice is received, and

- That the signed Notice may be returned by fax, email, campus mail, or US mail, and

- That research activity may not begin until the receipt of the signed Notice is received.

A copy of the emails transmitting Protocol Approval Notices will be also be sent to the investigator's Department Chair or Dean if the investigator is a Department Chair, and

The IRB will send an email acknowledgement that the signed Protocol Approval Notice has been received and that the investigator may now begin their research.